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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NOLAN, PATRICK J	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,075	TREACY, GEORGE	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-12 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-22-04 has been entered.

3. In view of the amendment to the claims submitted on 11-22-04, only the following rejections remain.

4. Claims 3-4, 7-8 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The monoclonal antibody cA2 recited in claims 3-4, 7-8 and 11-12 are essential to the claimed invention. The reproduction of monoclonal antibodies is an unpredictable event. The cA2 monoclonal antibodies and the cell line c168A which produces the cA2 monoclonal antibody, disclosed on page 7 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the monoclonal antibody or cell line, and it is not apparent if the monoclonal antibody is readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the monoclonal antibody producing hybridoma or cell line have been deposited under the Budapest Treaty and that the monoclonal antibody will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent whichever is longer.** See 37 CFR 1.806. If

the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the plasmid described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Applicant's arguments filed on 2-23-04 have been fully considered but are not found persuasive.

Applicant argues the cA2 monoclonal antibody is attainable by those of skill in the art in following the teachings of the specification.

While the Examiner concedes the variable region sequence for both the heavy and light chain are disclosed in Figure 16. The remaining issue is the constant domains. The specification clearly states the constant regions of the cA2 monoclonal antibody has the sequence of the human IgG1 κ immunoglobulin, which are readily available in the art.

The Examiner agrees the human IgG1 κ constant domain is well known, the problem is Applicant claims read upon full length monoclonal antibodies, as such, the 3 constant domains of the heavy chain are not disclosed. κ refers only to light chain sequences. In practicing the claims

the sequence of the both the heavy and light chain are required to make the full length cA2 monoclonal antibody.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 1-12 stands rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent 5,698,195 (AA), in view of Shah et al. (AY) and Lukacs et al. (AS), all of record, for reasons set forth in the paper mailed 8-21-03.

It is noted that the '195 also specifically teaches the use of chimeric antibodies which competitively inhibits the binding of TNF-alpha to the cA2 monoclonal antibody (see columns 11-12, in particular).

Applicant's arguments filed 11-22-04 have been fully considered but are not found persuasive.

The declaration under 37 CFR 1.132 filed 12-20-04 is insufficient to overcome the rejection of claims 1-12 based upon 35 USC 103 as set forth in the last Office action.

The declarant opinions were not found persuasive to remove the 35 USC 103 rejections because he did not address the primary reference in the rejection, the '195 patent. Since he did

not provide any evidence as to why the teachings of the '195 patent could not be used to treat asthma his conclusions were not found persuasive.

Applicant argues that two post dated filing references provide evidence that one of ordinary skill in the art would not have been able to predict using the teachings of the prior art that administration of anti-TNF antibody to a subject would be effective in treating asthma.

The standard for obviousness is what one of ordinary skill in the art would have recognized at the time the invention was made, not post dated. Applicant has provided no evidence demonstrating that one of skill in the art at the time the invention was made would not have had a reasonable expectation of success in treating asthma by administering an anti-TNF-alpha antibodies to humans suffering from asthma. Neither of the references disclosed by Applicant demonstrate the TNF-alpha has no role in asthma. Rudmann et al., reference clearly acknowledges the limitation of their findings to the mouse model used and Matheson et al., clearly teaches a role for TNF-alpha in TDI induced asthma.

The '195 patent clearly teaches that in diseases where TNF-alpha levels are abnormally high, an anti-TNF-alpha antibody can be used to neutralize the excess amount of TNF-alpha and thereby treat the disease in humans. Shah et al., teaches that TNF-alpha levels are 20 times greater in asthmatics then in control human patients. So motivation to administer an anti-TNF-alpha antibody is clearly present and both Shah et al., and the '195 patent teach a reasonable expectation of success in the treatment outcome.

6. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
February 18, 2005